SAS™ Rota Test is a rapid lateral-flow, membrane-based immunoassay for the qualitative detection of rotavirus antigen in human fecal specimens. SAS™ Rota Test aids in the diagnosis of acute gastroenteritis caused by rotavirus infection.

- CLIA Classification: Non-waived
- Simple to run—results within 15 minutes.
- Buffer and extraction tubes are provided in kit.
- Room temperature storage.
- 18-month shelf life.

CPT Code: 87425
Sensitivity: >98%
Specificity: >98%
Specimen: Stool
SAS™ Rota Test

Test Procedure

The pouch must be at room temperature before opening to avoid condensation of moisture on the membrane. Allow specimen and/or controls to reach room temperature prior to testing.

1. Remove the test device from the protective pouch and place it on a flat surface. Label the device with patient or control identifications.
2. Using a swab, add 30-50 mg of stool sample to tube containing the extraction buffer provided.
3. Dispense 4 drops (approximately 150µL) of the supernatant into the round sample well (see illustration). Wait for colored lines to appear.

Test Results

Read results after 15 minutes and no later than 30 minutes. Positive results may be observed in as short as 30 seconds depending on the concentration of the antigen.

The test is negative if a colored line only appears in the C (control) area. The test is positive if one colored line appears in the C (control) area and one line appears in the S (specimen) area.

(See package insert for detailed instructions.)

<table>
<thead>
<tr>
<th>Description</th>
<th>Cat. No.</th>
<th>Test/ Kit</th>
<th>Specimen</th>
<th>Application/Shelf Life</th>
<th>Sensitivity, Specificity</th>
<th>CLIA/ CPT Code</th>
<th>Results/ Minutes</th>
</tr>
</thead>
<tbody>
<tr>
<td>SAS™ Rota Test</td>
<td>069020</td>
<td>20</td>
<td>Stool</td>
<td>Detects wide range of Rotavirus serotypes (Shelf Life: 18 mos.)</td>
<td>&gt;98%, &gt;98%</td>
<td>Non-waived/ 87425</td>
<td>15</td>
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<tr>
<td>Control Set</td>
<td>069101</td>
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</tbody>
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